## REMARKS

Reconsideration and withdrawal of the rejections set forth in the Final Office Action dated March 15, 2004 are respectfully requested.

### I. Amendments

Claims 1-9 stand canceled.

Table 1 on page 8 is amended to omit column 3.

### II. Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-30 were rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. Specifically, in the absence of an explanation for the changes made to Tables 1 and 3 in Applicants prior amendment, the Examiner finds the amendments to be new matter.

As noted above, Table 1 is amended to omit column 3. Omission of column 3 obviates any allegation of new matter rejection with respect to correcting the table to correct the error in the heading from "Conc. phospholipids" to "Conc. phosphorus."

With respect to amendment of Tables 1 and 3 to correctly recite the drug/lipid ratio, the Examiner asks for an explanation for the "enormous discrepancy between the original values and the new values."

The values in these columns headed "Drug/lipid ratio" of the tables as originally filed were drug/phosphorus values determined from the values in columns 2 and 3 of the table. For example, in row 1 of Table 1, the drug concentration of 2.35 mg/mL divided by the phosphorus concentration of 1.50 mg/mL equals the value in row 1 of column 4, 1.57 (2.35/1.50 = 1.57).

Those of skill in the art would recognize that the values in the tables as originally filed are not drug/lipid ratios, since the values cannot be calculated based on the liposome compositions given. For example, the liposome composition with 89/5/6 lipid/pegylated-lipid/drug (row 1 of Tables 1, 3; page 7, line 26; page 10. line 37) has a molar drug to lipid ratio of 6/94, or 0.06. Clearly, the values in Tables 1 and 3 are incorrect.

Applicants submit that correction of the specification to recite the correct drug/lipid ratios for the disclosed compositions is not new matter. As the Examiner noted, drug/lipid ratios are simply the mole fraction of drug divided by the sum of the lipid mole fractions. The compositions are disclosed in the specification, and the drug/lipid ratios are an inherent characteristic of the disclosed compositions.

It is well-established in the case law that amendatory material is not new matter where it is concerned with an inherent characteristics of an illustrative product of an invention already sufficiently identified in the original patent disclosure. (In re Nathan, Hogg, and Schneider, 140 USPQ 601 (CCPA, 1964). The amendatory material provided here is directly related to an inherent characteristic of the composition described. Moreover, the amendatory material is readily derivable by a person skilled in the art of the claimed invention using the liposome formulations recited in the specification and, if needed, recognized sources (e.g., journal articles and trade information) to calculate the drug/lipid ratio. Thus, no new matter is introduced by these amendments to the specification.

## III. Rejections under 35 U.S.C. § 103

Claims 1-9 were rejected under 35 U.S.C. §103 as being obvious over Martin *et al.*, U.S. Patent No. 5,213,804 in view of Mori *et al.* (*Cancer Chemother. Pharmacol.*, 35:447 (1995)).

Claims 1-9 were rejected under 35 U.S.C. §103 as being obvious over Martin *et al.* in view of Mori *et al.* further in view of Kassis, U.S. Patent No. 5,077,034.

Claims 1-9 stand canceled.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103.

## VI. Conclusion

In view of the foregoing, the claims pending in the application comply with the requirements of 35 U.S.C. § 112 and patentably define over the applied art. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 564-2867.

Respectfully submitted,

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